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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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Anthony J. Kosinski

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David W. Highet, VP & Chief IP Counsel

Becton, Dickinson and Company

1 Becton Drive

MC 110

Franklin Lakes, NJ 07417-1880

EXAMINER

HOLLOWAY, IAN KNOBEL

ART UNIT

PAPER NUMBER

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/594,335	Applicant(s) KOSINSKI, ANTHONY J.	
	Examiner IAN K. HOLLOWAY	Art Unit 3763	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 November 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-32 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-9, 12-25 and 29-32 is/are rejected.
- 7) ☒ Claim(s) 10, 11, 27 and 28 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on _____ is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Amendment

Receipt is acknowledged of applicant's amendment filed (11/5/09). Claims 1-32 are pending and an action on the merits is as follows.

Applicant's arguments with respect to claims 1-32 have been considered but are moot in view of the new ground(s) of rejection.

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

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invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

4. Claims 1-8, 16-21 are rejected under 35 U.S.C. 103(a) as being anticipated by Pagay et al. (US Patent 5411488), herein after referred to as P, in view of Horita et al. (US patent 6796217), herein after referred to as Ho.

Regarding **Claim 1**, P discloses: a barrel (**20**, the barrel) including a cylindrical side wall (**21**) having an inside surface defining a chamber for retaining fluid, an open proximal end (**24**, the open end located near the finger grips) and a distal end (**22**, tapered tip) including a distal wall with a tip extending distally therefrom having a passageway (**Fig. 2**, the barrel) therethrough in fluid communication with said chamber; a plunger (**50**, plunger) including an elongate body portion having a proximal end and a distal end, a stopper (**30**) slidably positioned in fluid-tight engagement with said inside surface of said barrel for driving fluid out of said chamber by movement of said stopper relative to said barrel, said elongate body portion extending outwardly from said open proximal end of said barrel;

P fails to teach the means for moving additional fluid

Ho teaches means for moving (**Fig. 5A-D**, plunger rod tip) additional fluid distally in said passageway at the completion of the flush procedure after distal motion of said plunger with respect to said barrel has stopped.

It would have been obvious to one of ordinary skill in the art at the time of the invention was made to use the design as taught by **Ho**, since **Ho** states at column 1, lines 45-64 that such modification would reduce dripping. Thus, it would have been obvious to one of ordinary skill in the art to apply the construction as taught in **Ho**, to improve the device of **P** for the predictable result of reducing mess formation when using the device.

Regarding **Claim 2**, **P** discloses: said stopper including a distal end having a distal wall (**32**, convex side) and a cavity (**34**, interior) therein defining an inside surface and a proximal end, said distal wall being flexible enough to collapse at least partially into said cavity under the liquid pressure of a flush procedure and to move back toward its original shape at the completion of the flush procedure to force additional fluid into said passageway..

Regarding **Claim 3**, **P** discloses: a distal tip on said distal end of said plunger is connected to said stopper. (**Fig. 4**).

Regarding **Claim 4**, **P** discloses: a sealing surface around its periphery in fluid-tight engagement with said inside surface of said barrel. (**Fig. 2**).

Regarding **Claim 16**, **P** discloses: means for allowing air trapped in the stopper cavity to escape as said distal wall collapses. (**Fig. 3**).

Regarding **Claim 17**, **P** discloses: an aperture (**Fig. 3**, the hole in the back) in said plunger communicating with said cavity of said stopper..

Regarding **Claims 5-8**, **P** discloses the invention claimed as stated above except for Liquid pressure, volume, and delivery time.

It would have been obvious to one having ordinary skill in the art at the time of the invention was made to use an optimum liquid pressure, volume, and delivery time, since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art. In re Boesch, 617 F.2d 272, 205 USPQ 215 (CCPA 1980).

Regarding **Claim 18-19**, **P** discloses the invention claimed as stated above except for the flush solution

It would have been obvious to one having ordinary skill in the art at the time the invention was made to use a flush solution, Since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. In re Leshin, 125 USPQ 416.

Regarding **Claim 20**, **P** discloses: a tip cap releasably connected to said tip of said syringe barrel for sealing said passageway. (**22**, the tip is capped after the device is filled).

Regarding **Claim 21**, **P** discloses: thermoplastic elastomers, natural rubber, synthetic rubber, thermoplastic materials and combinations thereof. (**Column 1, line 44**, elastomeric plunger).

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5. Claims 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over P in view of Grimard (US Patent 5795337), herein after referred to as G.

Regarding **Claim 9**, **P** discloses the invention claimed as stated above except for the conical shape

However, **G** teaches a conically shaped distal surface and said inside surface of said barrel at said distal wall is conically shaped. **(27, conical)**

It would have been obvious to one of ordinary skill in the art at the time of the invention was made to use the design as taught by **G**, since **G** states at column 1, lines 26-40 that such modification would reduce medicine waste. Thus, it would have been obvious to one of ordinary skill in the art to apply the construction as taught in **G**, to improve the device of **P** for the predictable result of reducing long term costs of using the device.

Regarding **Claim 22**, **G** discloses: a needle assembly including a cannula having a proximal end, a distal end and a lumen theretluough, and a hub having an open proximal end. containing a cavity and a distal end attached to said proximal end of said cammla so that said lumen is in fluid communication with said cavity, said needle assembly being removably attached to said tip of said barrel through engagement of said tip to said cavity so that said lumen is in fluid communication with said chamber. **(49)**

6. Claims 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over P in view of Eykmann et al. (US Patent 5620423), herein after referred to as E.

Regarding **Claim 12**, **P** discloses the invention claimed as stated above except for the projection.

However, **E** teaches a proximally directed projection (**Fig. 2**) configured to compress when said stopper is in a collapsed position and to urge said distal wall from said collapsed position toward its original shape

It would have been obvious to one of ordinary skill in the art at the time of the invention was made to use the construction as taught by **E**, since **E** states at column 2, lines 27-34 that such modification would provide a controlled discharge. Thus, it would have been obvious to one of ordinary skill in the art to apply the construction as taught in , to improve the device of **P** for the predictable result of making it more effective.

Regarding **Claim 13**, **E** discloses: at least one rib on said inside surface of said stopper at said distal wall configured to deflect when said stopper is in a collapsed position and urge said distal wall from said collapsed position toward its original shape. **(15)**.

Regarding **Claim 14**, **E** discloses: an area of reduced thickness (**13**, the bend) to lower the pressure required for said distal wall to collapse.

Regarding **Claim 15**, **E** discloses: circular groove (**13**, the groove is a ring on the interior) in said inside surface at said distal wall of said stopper.

Regarding claims 23-26, and 29-32, see rejections for claims 1-9 and 12-22

Allowable Subject Matter

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7. Claims 10-11 and 27-28 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Response to Arguments

Applicant states, the claims overcome P, and that rejection has been withdrawn, however the claims remain rejected over P in view of Ho.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to IAN K. HOLLOWAY whose telephone number is (571)270-3862. The examiner can normally be reached on 8-5, Monday-Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nicholas D. Lucchesi can be reached on 571-272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Ilan K Holloway/
Examiner, Art Unit 3763

/Nicholas D Lucchesi/
Supervisory Patent Examiner, Art Unit 3763